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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/577,353

04/28/2006

Lennart Jonsson

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EXAMINER

BHATIA, AARTI

ART UNIT

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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/577,353	<b>Applicant(s)</b> JONSSON, LENNART	
	<b>Examiner</b> Aarti Bhatia	<b>Art Unit</b> 3763	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-20 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. ____.                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>4/28/2006</u> .   | 6) <input type="checkbox"/> Other: ____.                          |

### DETAILED ACTION

This is the initial Office Action based on the 10/577,353 application filed on 4/28/2006.

Claims 1-20, as amended on 4/28/2006, are currently pending and have been considered below.

#### ***Double Patenting***

1. A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

2. Applicant is advised that should claim 5 be found allowable, claim 20 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing

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one claim to object to the other as being a substantial duplicate of the allowed claim.

See MPEP § 706.03(k).

***Claim Rejections - 35 USC § 102***

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 1-3, 6-9, 14, and 16 are rejected under 35 U.S.C. 102(b) as being anticipated by WO 97/21459 to Kornerup.

Kornerup discloses the following:

1. A device for preventing axial movement of an elongated member (5), such as a cannula needle, applied through the skin of a mammal at a puncturing position, said device comprising a plaster (41) designed to cover the surface around the puncturing position and having at least an adhesive layer (page 8, line 21) for securing it to the skin as well as an opening (44) through the layer thereof for the passage of said elongated member therethrough, the device further comprising means (31) secured to the plaster and adapted to clamp around said elongated member (5) when the elongated member is applied through the skin of a mammal and the plaster is applied on the surface around said puncturing position, wherein said clamping means (31) is thin and substantially flat and provided with a lateral opening (32) for laterally introducing a said elongated member between clamping positions (34) thereof, and said clamping means

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includes parts of substantially rigid material provided with clamping portions (34) adapted to bear against said elongated member.

2. A device according to claim 1, wherein said clamping means (31) is made of material being substantially more rigid than the material forming the plaster (41).

3. A device according to claim 1, wherein surfaces through which the clamping portions (34) are adapted to bear against a said elongated member are made of a substantially rigid material (inferred from figure 4a).

6. A device according to claim 1, wherein said plaster (41) is provided with a pocket formed between two adjacent layers (21, 41) thereof and housing said clamping means (31).

7. A device according to claim 6, wherein said plaster (41) comprises at least two additional layers besides said adhesive layer, and said pocket is formed between two such additional layers (see figure 4a).

8. A device according to claim 7, wherein the plaster (41) comprises a carrier layer arranged on top of the adhesive layer and an uppermost coating layer, and said pocket is formed between said carrier layer and coating layer (see figure 4a).

9. A device according to claim 1, wherein said clamping means (31) is transferrable between an inactive state (figure 1) allowing a said elongated member to be introduced between clamping portions (34) thereof and an active state (figure 2) in which said clamping portions bears under tension against a said elongated member.

14. A device according to claim 1, wherein said plaster opening (44) is formed by a lateral slot (42) into the plaster (41) for enabling introduction of said elongated

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member into said opening after the elongated member has been applied through the skin of a mammal.

16. A device according to claim 2, wherein surfaces through which the clamping portions (34) are adapted to bear against said elongated member are made of a substantially rigid material.

***Claim Rejections - 35 USC § 103***

5. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

6. Claims 5, 10, 11, and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kornerup.

Kornerup discloses a device according to claims 1 and 9, but is silent to the material used for the clamping means.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to use a shape memory metal for the clamping means, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice.

*In re Leshin*, 125 USPQ 416.

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7. Claims 4 and 17-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kornerup in view of U.S. Patent No. 6,231,548 to Bassett.

Kornerup discloses the device according to claims 1 and 16, but fails to teach sharp gripping edges on the clamping means.

Bassett teaches a securing device for an IV that has sharp gripping edges (70) on the clamping means (14)

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the clamping means of Kornerup with the sharp grippers of Bassett to further secure the tubing within the clamping means.

8. Claims 12 and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kornerup in view of U.S. Patent No. 6283945 to Bierman.

Kornerup discloses the device according to claim 9, but fails to teach a spring member.

Bierman teaches an anchoring system for a medical article wherein the clamping means comprises at least one spring member (42) connected to said clamping portions or urging them towards each other, wherein it comprises a blocking member (74) adapted to hold the clamping portions apart in said inactive state for allowing introduction of said elongated member (8) therebetween and when released allowing said spring member (42) to transfer the clamping means to the active state.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the clamping means of Kornerup with the spring of

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Bierman to allow for releasable engagement with the elongated member (column 4, lines 50-59).

9. Claim 15 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kornerup in view of U.S. Patent No. 6,375,639 to Duplessie et al.

Kornerup discloses a device according to claim 1, but fails to teach an arm band.

Duplessie teaches an intravenous stabilizing device with an elongated flexible, preferably adjustable, such as by being elastic, band-like member (36, 76) secured to the plaster and adapted to be applied around a body part of a mammal on which said puncturing position has been applied for assisting the adhesive layer of the plaster in holding the plaster secured around the puncturing position (column 5, lines 19-30).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the plaster of Kornerup with the arm band of Duplessie to further hold the device in place without the use of tape on the patient (column 1, lines 5-15).

### ***Conclusion***

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. See PTO-892.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Aarti Bhatia whose telephone number is (571) 270-5033. The examiner can normally be reached on Monday-Thursday 8:00am - 6:30pm.



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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nicholas Lucchesi can be reached on (571) 272-4977. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at (866) 217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call (800) 786-9199 (IN USA OR CANADA) or (571) 272-1000.

/Aarti Bhatia/  
Examiner, Art Unit 3763

/Nicholas D Lucchesi/  
Supervisory Patent Examiner, Art Unit 3763